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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,558	09/14/2001	Keiko Matsumoto	52740	7124
7590	11/30/2004		EXAMINER	
RONALD I. EISENSTEIN NIXON PEABODY, LLP 101 FEDERAL STREET BOSTON, MA 02110-1832			SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/936,558	MATSUMOTO ET AL.
	Examiner	Art Unit
	Humera N. Sheikh	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 19-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 19-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR §1.114 filed 01/27/04, the request for extension of time (3 months-granted), the Amendment and Applicant's Arguments/Remarks, all filed 07/26/04 is acknowledged.

Claims 19-46 are pending. Claims 19, 32 and 37 have been amended. Claims 1-18 have previously been cancelled. Claims 19-46 are rejected.

New Matter

The amendment filed 01/27/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The phrase limitation of claim 19, line 3, which recites "*in the absence of any solvent*" introduces new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims now presented recite "*in the absence of any solvent*". However, a detailed review of the instant specification indicates a lack of support for this amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,480,175 in view of Kondo *et al.* (US Pat. No. 5,098,907).

The GB reference teaches a pharmaceutical preparation in the form of coated tablets prepared by the direct compression of an active, wherein the composition comprises a lubricant, such as talc, magnesium stearate or stearic acid, an adjuvant, such as lactose or anhydrous calcium phosphate, and a disintegrant, such as starch (see column 3, lines 23-63). The tablet composition exhibits good compression characteristics, having no decrease of activity during the compressing step and has a desirable rate of disintegration (col. 3, lines 1-15).

The reference is silent as to the use of silicic anhydride and is silent regarding the angle of repose. With regards to the silicic anhydride, it is the position of the Examiner that one of ordinary skill in the art could substitute silicic anhydride with talc, magnesium stearate or the like, as they are acceptable equivalents of silicic anhydride. The selection of a known material based on its suitability for its intended use is obvious, absent a clear showing of unexpected results attributable to the Applicant's specific selection.

Regarding angle of repose, no criticality is observed in the angle of repose since a product is being claimed and it is the patentability of the product that must be established. Moreover, one skilled in the art can readily determine a suitable angle of repose. Such skill is also evident from the reference of Kondo *et al.*

Kondo *et al.* ('907) teach a powdery pharmaceutical composition comprising a fluidizer, light anhydrous silicic acid, that functions to improve the flowability of the composition, whereby the composition exhibits an angle of repose of 40° (see reference column 4, lines 11-17); (column 7, lines 22-45) and Examples. The composition also contains excipients, such as

starch, lactose, magnesium stearate and the like (col. 5, line 5 – col. 7, line 21). Kondo *et al.* teach at col. 7, lines 10-17, that by the addition of magnesium stearate and light silicic anhydride, an improvement in the flowability was observed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the light anhydrous silicic acid taught by Kondo *et al.* within the formulation of GB ‘175 if the intended purpose was to improve the overall flowability of the compressed formulation since Kondo *et al.* explicitly teaches a composition comprising light silicic anhydride, wherein an improvement in the flowability was observed by the addition of the silicic anhydride. The expected result would be a tablet formulation exhibiting improved flowability and disintegration, as similarly desired by the Applicant.

Response to Arguments

Applicant's arguments filed 01/27/04 have been fully considered but they are not persuasive.

Applicant argued, “The GB reference describes coated tablets where the pharmacologically active agent must be mixed with maltose. ‘175 is restricted to direct compression of the maltose-containing mixture into a tablet. ‘175 in no way makes it obvious to exclude the use of a solvent in preparing a fast-disintegrating tablet.”

These arguments have been fully considered, but were not found persuasive. With regards to the inclusion of maltose, the Examiner notes that the instant claims utilize “comprising” claim language and thus, the inclusion of additional ingredients, aside from those

recited, are permitted in the formulation. Additionally, the GB reference utilizes a dry granulation process whereby desirable rate disintegrations are preferred and thus, Applicant's arguments that the 'GB reference does not exclude a solvent' were not found persuasive.

Applicant's arguments with respect to the JP 10114655 reference have been considered, but are moot in view of the new grounds of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh *NN8.*

Patent Examiner

Art Unit 1615

November 29, 2004

[Signature]
THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600